From the Canadian Paediatric Society

In support of a compensation plan for vaccine-associated injuries

Infectious Diseases and Immunization Committee,* Canadian Paediatric Society

In the 1980s Canada's childhood immunization programs have been so successful that the target illnesses are seen infrequently, some not at all. Lacking visible reminders of the dangers of these illnesses, parents today are less certain of the benefits of vaccination than were parents 1 or 2 decades ago and are more concerned about the safety of vaccines being offered to their children. The vaccines routinely used in Canada are much safer than the diseases they prevent, but they are not perfect. Given that vaccines must contain the key portions of bacteria or viruses necessary to induce protective immunity, perfectly safe vaccines may not be attainable. Nevertheless, efforts must be continued to fashion vaccines as safe as contemporary technology will permit.

To maintain a high level of public confidence in routine immunization programs, three types of activity are important. First, education of the general public regarding the benefits and actual (i.e., undistorted) risks of vaccination must continue. Second, development of safer vaccines must receive higher priority within the medical research community and national funding agencies. Third, recipients of government-approved vaccines should be assured that generous help will be provided if they experience a serious adverse event following vaccination. It is to the last point that this proposal is addressed.

*Members: Drs. Margaret I. Hunter (director responsible), Montreal Children's Hospital; David W. Scheifele (chairman and principal author), BC Children's Hospital, Vancouver; Robert A. Bortolussi, Izaak Walton Killam Hospital for Children, Halifax; Ronald Gold, Hospital for Sick Children, Toronto; Normand Lapointe, hôpital Sainte-Justine, Montreal; Noni E. MacDonald, Children's Hospital of Eastern Ontario, Ottawa; and Elaine L. Mills, Montreal Children's Hospital. **Consultants**: Drs. Pierre Déry, Centre hospitalier de l'université Laval, Quebec; R.P. Bryce Larke, University of Alberta, Edmonton; J.H. Victor Marchessault, Children's Hospital of Eastern Ontario, Ottawa; and John R. Waters, Alberta Department of Social Services and Community Health, Edmonton. **American Academy of Pediatrics liaison**: Dr. Philip Brunell, University of Texas, San Antonio*

Reprint requests to: Infectious Diseases and Immunization Committee, Canadian Paediatric Society, Children's Hospital of Eastern Ontario, 401 Smyth Rd., Ottawa, Ont. K1H 8L1

Rationale for a compensation plan

It is highly likely that even the most sophisticated vaccines will carry some risk of adverse reaction, given their content of microbial antigens. The realizable objective of vaccine development is greater safety, not perfection. It is inevitable that a few recipients of government-approved vaccines will experience serious adverse reactions of idiosyncratic origin, despite correct vaccine manufacturing and administration procedures.

How can society help such victims? To date, the only means to obtain compensation beyond that routinely provided by provincial health care plans has been litigation. The courts have been sympathetic in these situations but have struggled hard to place fault, bringing forth new concepts such as "failure of the provider to warn of possible risks". Vaccines have been judged dangerous and defective despite meeting all government regulations. The hazard in this course is already evident in the United States, where vaccine costs have skyrocketed to cover manufacturers' rising liability insurance rates, vaccine supplies have been threatened as some manufacturers quit the marketplace, and vaccine development by industry has been stifled. Canadian manufacturers currently face suits claiming tens of millions of dollars in damages. This industry has a relatively low profit margin and will be seriously destabilized by relatively few large findings against it. The publicity associated

with these actions feeds the general concern about vaccine safety, which in turn could affect vaccine acceptance rates and disease control. Clearly, a better solution is needed for vaccine-damaged people.

Outline of a Canadian plan

In outlining the proposed plan, the Canadian Paediatric Society (CPS) drew upon the designs of plans in use in Quebec, Japan, France and West Germany (Appendix I).

The CPS favours a compensation plan for vaccine-associated injuries with the following features.

- All active immunizing agents (vaccines) licensed for use in Canada would be included.
- Compensation would be given to those who suffer serious damage, such as that causing lengthy hospitalization, prolonged or permanent injury, or death.
- Compensation would be provided for costs and losses beyond the scope of existing health care and education plans, including costs of special remedial devices, therapy and transportation, caretakers' allowances in recognition of the extra costs of attending or caring for an injured person, disability pensions or awards, proportionate to loss of capacity, and death benefits.

A basic premise of the plan would be legislation to declare that no fault exists when injury follows administration of a vaccine that meets all government regulatory standards and is given correctly, with due consideration to any contraindications and after reasonable disclosure of potential risks to the recipient. People injured in such circumstances (the minority) could turn to the plan for compensation, without facing extensive legal costs or long delays. In situations in which medical or manufacturing negligence might exist (the minority), injured people could either seek a legal remedy or choose the plan. If litigants are found by the courts to have been injured in a "no-fault" situation (as above), they could still seek compensation from the plan. In cases in which liability is established, the courts will perhaps be guided by the provisions of the plan in determining the plaintiff's award.

This approach would preserve the right of injured people to seek redress when negligence exists, compensate the larger number of people injured without fault and recognize that vaccines are a unique commodity that cannot be made perfectly safe. With a clearer definition of the grounds for litigation, both providers and manufacturers of vaccines could again feel secure if their service or product is satisfactory.

Claims review process

A mechanism would be required to review claims to the plan. It must be appreciated that some adverse events that follow vaccination occur by coincidence. In children, for instance, postvaccination adverse neurologic events may actually be due to intercurrent infection, brain malformation or evolving brain disorders. Some investigation of relevant alternative causes should be required, because the existence of a plan might be a deterrent to discovering other, noncompensable causes of injury. A time would have to be defined beyond which injury is unlikely to be the result of a specific vaccine.

Adverse events of a type known not to result

Table I — Examples of serious adverse reactions to vaccines

Vaccine	Reaction	Frequency (and outcome)
Routinely used		
Diphtheria toxoid	Anaphylaxis	Rare*
Tetanus toxoid	Anaphylaxis	Rare*
Pertussis	Hyporesponsiveness	1/1750 injections (complete recovery)
	Convulsions	1/1750 injections (complete recovery)
	Encephalopathy	1/110 000 injections (recovery in 67% of cases)
Poliomyelitis		
Inactivated	Anaphylaxis	Rare*
Live attentuated	Paralysis	1/4.8 million doses; 1 contact case/3.7 million doses distributed
Measles	Anaphylaxis	Rare*
	Encephalitis	1/million doses
Mumps	Anaphylaxis	Rare*
Rubella	Anaphylaxis	Rare*
	Chronic or recurrent arthritis	Rare in children
Selectively used		
Bacille Calmette-Guérin (BCG)	Severe osteitis	Rare
	Generalized BCG infection	1/million vaccinees
Influenza	Anaphylaxis	Rare
Rabies (human diploid cell)	Anaphylaxis	1/10 000 vaccinees

*Estimated fatality rate 1/10 million injections.

from vaccination should be excluded. These events should be considered and defined at the inception of the plan by an appropriate group of medical experts.

Individual cases should be reviewed by an expert medical panel whose objective is to confirm or deny a reasonable probability of a causal association between vaccination and injury, given that precise determination of cause of injury will often be impossible. An appeal mechanism should be created, involving a separate panel of experts who take a fresh look at the case.

Accepted claims would need to be processed for compensation, a task that is probably best done by a compensation board whose members are skilled in such matters. The board would require an objective and detailed assessment of injury and disability and an accounting of incurred and projected costs. The board should provide compensation according to predetermined formulas that allow some consideration of individual circumstances. Settlements should be manifestly fair. The claims settlement process should also be subject to appeal. Compensation should begin as soon as possible. Claims involving brain damage in children would have to be reviewed periodically, because the final degree of impairment might not be assessable for some time.

Administrative considerations

For such a plan to be effective, it should be available throughout Canada, with consistent provisions in all jurisdictions. This suggests that the initial structuring of the case review and compensation procedures should be done by expert committees drawn from all jurisdictions. Provinces could then set up case review panels and compensation boards to apply these principles.

Final perspective

It is not the purpose of the CPS to set forth a detailed compensation plan or to limit possible mechanisms for administering and financing it. The general outline is shaped by the circumstances involved. We believe that such a plan would not only be fairer to vaccinees but would also help to maintain confidence in the immunization program. The unique nature of vaccines as a valuable but inherently imperfect commodity must be recognized by society before the vaccine industry is weakened by the tort system. Vaccinees injured because of negligence of the manufacturer or provider would retain access to the tort system, as is proper. Vaccinees injured without fault (maloutcome rather than malpractice) would be guaranteed fair compensation. The ground rules for all parties involved would become clear.

With an annual birth cohort in Canada of about 400 000 infants, the number of serious adverse reactions following vaccination (Table I) is estimated to be fewer than two dozen, with major support required in only five or six cases. These estimates include about 18 episodes annually of encephalopathy occurring within 7 days after pertussis vaccination (but not necessarily caused by it), with 5 or 6 episodes resulting in permanent sequelae.[1] In addition, one case of measles-vaccine-induced encephalitis can be expected every 2.5 years, one fatal anaphylactic reaction to injected vaccines every 4 years and one case of paralysis due to oral poliomyelitis vaccine every 3 to 4 years. Although the number of people involved is small, their injury is tragic. Social justice requires that such people, who accepted vaccination in good faith, receive fair compensation. Surely it is time for all provinces to reinforce their immunization programs with a proper safety net.

Reference

1. Miller DL, Ross EM, Alderslade R et al: Pertussis immunisation and serious acute neurological illness in children. *Br Med J* 1981; 282: 1595–1599

Appendix I — Provisions of some existing compensation plans

- Quebec: Provides compensation for any serious permanent damage resulting from a licensed vaccine on a "no-fault" basis, comparable to provincial Automobile Insurance Act. Does not preclude access to civil proceedings, but awards must be repaid if plaintiffs are successful in court.
- Great Britain: Single award of £10 (tax free) to people severely disabled as a result of vaccination against specified diseases. Includes a central expert review panel that examines independent assessments of case histories and disability. Appeal mechanism provided.
- Japan: Covers damage caused by compulsory vaccines. Provisions include medical allowance, caretaker's allowance, disability pension and funeral grant. A national expert committee reviews applications.
- France: Covers damage caused by compulsory vaccines. Compensation is determined by a central tribunal and covers economic and noneconomic losses, including future support and help for parents.
- West Germany: Covers damage caused by all officially recommended vaccines. Provides coverage for medical and other costs. Disability pension based on federal scheme for workers. Probability of a causal relation is sufficient to establish a claim.
- Switzerland: Covers damage caused by recommended vaccines, in so far as expenses are not covered by another plan.
- Denmark: Covers damage caused by specified vaccines. Disability pension paid after age 15. Lump sum for disability of 5% to 50%, pension for greater disability.